REMARKS

Applicants thank Examiner Belyavskyi for the telephone conference held on July 21, 2008 with Applicant's representative, Kelli Watson Francuzenko, Thomas Cirrito (Director of Operations for Licensee, Stemline Therapeutics, Inc.) and Jacqueline Benn (Licensee's representative) to discuss the issues outstanding in the present non-final Office Action, mailed January 25, 2008. During the telephonic interview, the Examiner explained the rationale for the restriction requirement and Applicants discussed the possibility of modifying the restriction to combine groups for the reasons provided below.

Applicants note that this is the second telephone conference to review the issues in present non-final Office Action. The first telephone conference was held on May 27, 2008 with Examiner Perreira, and Applicant's representative, Kelli Watson Francuzenko, Thomas Cirrito (Director of Operations for Licensee, Stemline Therapeutics, Inc.) and Jacqueline Benn (Licensee's representative). Applicants note that the second interview with Examiner Belyavskyi was necessitated by the USPTO's decision to change the assigned art unit for the instant application in the middle of prosecution.

Applicants wish to correct the record of the first telephone conference held on May 27, 2008. The Summary of Record of Interview should state in the second sentence on the Continuation Sheet, "Applicant asserts that the method of group **III** and IV are combinable as the method of purging requires the method of impairing." The last sentence of the Summary should state, "Applicant asserts that the groups III, IV, **VII,** VIII, V and IX are combinable as they [have] overlap, such as all requiring an antibody that selectively binds to CD123."

Claims 11-89 are pending in the present application. Applicant has amended claims 16, 19 and 22. Applicant has also added new claims 90-92.

Amendments to claims 16 and 19 are to correct minor grammatical errors. Support for the amendment to claim 22 and new claims can be found in the specification as filed originally at, *e.g.*, page 4, *ll.* 15-20; and page 6, *ll.* 10-12. Thus, the claim amendments and new claims do not constitute new matter. Claims 11-92, therefore, will be pending upon entry of this Amendment.

Applicant respectfully requests that the remarks and amendments be considered and made of record in the present application.

I. Applicant Traverses the Restriction Requirement and Requests That Certain Inventions Be Re-Grouped

Claims 11 to 89 have been subjected to a restriction requirement as follows:

Group I: Claims 11-15, 18-21, 27-44 and 89, as drawn to compositions for impairing hematologic cancer progenitor cells that express CD123, but do not significantly express CD131.

Group II: Claims 16, 17 and 46-48, as drawn to an assay for detecting the presence of hematologic cancer progenitor cells that express CD123, but do not significantly express CD131.

Group III: Claims 22 and 49-57, as drawn to a method for purging hematologic cancer progenitor cells that express CD123, but do not significantly express CD131.

Group IV: Claims 23 and 56-66, as drawn to a method for impairing cancerous progenitor cells that express CD123, but do not significantly express CD131 in a sample.

Group V: Claims 24-26 and 67-69, as drawn to a method of purging cancerous progenitor cells that express CD123, but does not significantly express CD131, in a patient in need thereof.

Group VI: Claims 71, 75 and 79-88, as drawn to a composition for impairing a hematologic cancer progenitor cell that expresses CD123, but does not significantly express CD131 as examined by flow cytometry.

Group VII: Claims 72 and 76, as drawn to a method for impairing cancerous progenitor cells, but does not significantly express CD131 as examined by flow cytometry.

Group VIII: Claims 73 and 77, as drawn to a method for purging hematologic cancer progenitor cells, but does not significantly express CD131 as examined by flow cytometry.

Group IX: Claims 74 and 78, as drawn to a method for purging cancerous progenitor cells, but does not significantly express CD131 as examined by flow cytometry.

Applicant respectfully notes that claim 45 has been omitted from Group I. On April 29, 2008, Examiner Perreira confirmed in a telephone call with Applicant's representative that claim 45 should be in Group I.

Applicants request a modification of the restriction requirement to combine certain groups of claims, as the claimed subject matter is substantially overlapping and would not

require separate fields of search, and as such, would not constitute an undue burden on the Examiner. (MPEP §808.02(c)).

In particular, Applicants request reconsideration of the restriction in that the claims of Groups IV (claims 23 and 56-66) and VII (claims 72 and 76) be recombined into one group and examined on the merits in the instant application. Both groups claim a method of impairing cancerous progenitor cells wherein the progenitor cells express CD123, but do not significantly express CD131 and both groups have claims which specify that this expression is determined by flow cytometry (Group IV: claim 58 and Group VII: claim 72). Both groups require the administration of a composition comprising an antibody and a conjugate, wherein the composition binds selectively to CD123 (Group IV: claim 23) or the antibody selectively binds CD123 (Group VII: claim). Further, both groups have claims which require that the antibody and the cytotoxic agent be conjugated (Group IV: claim 59 and Group VII: claim 72). For these reasons, and as summarized in the chart below, Applicants assert that the groups would not require separate fields of search because they are all classified in the same art class 424.

Group	Method	Target Cells	Agent	Exposed Cells
Group IV (Cl. 23, 58-66)	Method of **impairing**	Cancerous progenitor cells that express CD123, not CD131 (as examined by flow cytometry, see dep. claim 58))	Antibody and cytotoxic agent Antibody is a monoclonal antibody, $F(ab')_2$, Fab or Fv (Claim 60)	Bone marrow or peripheral blood
Group VII (Cl. 72, 76), new Cl. 91	Method of **impairing**	Cancerous progenitor cells that express CD123, not CD131 as examined by flow cytometry	Antibody and cytotoxic agent Antibody is a monoclonal antibody, $F(ab')_2$, Fab or Fv (new claim 91)	Bone marrow or peripheral blood

In addition, Applicants request a modification of the restriction in that claims of Groups III (Claims 22 and 49-57) and VIII (Claims 73 and 77) be recombined into one group and examined on the merits in the instant application. Both groups claim a method of purging hematologic cancerous progenitor cells wherein the progenitor cells express CD123, but do not significantly express CD131 and both groups have claims which specify that this expression is determined by flow cytometry (Group III: claim 49 and Group VIII: claim 73). Both groups require the administration of a composition comprising an antibody and a

conjugate, wherein the composition binds selectively to CD123 (Group III: claim 22) or the antibody selectively binds CD123 (Group VIII: claim 77). Further, both groups have claims which require that the antibody and the cytotoxic agent be conjugated (Group III: claim 51 and Group VIII: claim 73). For these reasons, and as summarized in the chart below, Applicants assert that the groups would not require separate fields of search because they are all classified in the same art class 424.

Group	Method	Target Cells	Agent	Exposed Cells
Group III (Cl. 22, 49-57)	Method of purging	Hematologic cancer progenitor cells that express CD123, not CD131 (as examined by flow cytometry, see dep claim 49)	Antibody and cytotoxic agent Antibody is a monoclonal antibody, $F(ab')_2$, Fab or Fv (claim 52)	Bone marrow or peripheral blood
Group VIII (Cl. 73, 77), new Cl. 92	Method of purging	Hematologic cancer progenitor cells that express CD123, not CD131 as examined by flow cytometry	Antibody and cytotoxic agent Antibody is a monoclonal antibody, $F(ab')_2$, Fab or Fv (new claim 92)	Bone marrow or peripheral blood

Should the Examiner determine that the claims of Groups IV and VII and the claims of Groups III and VIII be recombined, the Applicants further request that the restriction be modified so that the claims of Groups III, IV, VII and VIII are combined into one group and examined on the merits in the instant application. The claims of Groups IV and VII relate to a method of *impairing* cancerous progenitor cells, and the claims of Groups III and VIII relate to a method of *purging* cancerous progenitor cells. Applicants point out that purging refers to an *ex vivo* method for impairing target cells, and therefore the claims of Groups IV and VII would encompass the *ex vivo* method of purging. Therefore, the combination of Groups III, IV, VII and VIII, would not result in a need to search separate fields and would not present an undue burden to the Examiner. Thus Applicants request that the claims of Groups III, IV, VII and VIII be combined and examined on the merits in the instant application.

While Applicants traverse the restriction requirement for the reasons set out above, in order to be fully responsive, Applicants elect to prosecute the claims of Groups III, IV, VII and VIII should the Examiner reconsider the restriction and recombine these groups. Should the Examiner not recombine Groups III, IV, VII and VIII, but reconsider the restriction and

recombine Groups IV and VII, Applicants elect to prosecute the combined Groups IV and VII. Finally, should the Examiner not reconsider the restriction and not recombine the claims of Group IV with any other group, Applicants elect to prosecute the claims of Group IV.

Applicants also request that the restriction be further modified to combine Groups I and VI, as each of these groups are drawn to compositions that comprise an antibody that selectively binds CD123 and a cytotoxic agent. Both groups have claims that specify that the antibody may be a monoclonal antibody, $F(ab)_2$, Fab or Fv. Applicants reserve the right to request rejoinder of the product claims, once the process claims are found to be allowable.

CONCLUSION

Applicant respectfully requests that the above-made remarks and amendments be entered and made of record in the present application. If any issues remain in connection herewith, the Examiner is respectfully invited to telephone the undersigned to discuss the same

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

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